REMARKS

Claims 19, 21 – 30 and 33 - 35 are currently pending.

All previous rejections have been withdrawn; however, two new rejections have been asserted in this Office Action.

First, the Office Action presents a new rejection under §112, first paragraph, written description requirement.

As the basis for this rejection, the Examiner now asserts for the first time that the claims contain "new matter", citing the phrase "suffering from or susceptible to a prion disease" as being new.

Applicants are amazed that such a rejection appears at this late stage of prosecution. Claim 19, the claim in which the phrase is used, was added by amendment on March 20, 2003. Applicants adamantly assert that this rejection is baseless (there is no reason given in the Office Action for this rejection), and in any event, if sustainable, should have been raised five years prior to this Office Action. Unless the Examiner can explain and support this rejection, it should properly be withdrawn.

Second, the Office Action now, for the first time, raises a novelty rejection, under §102(b) of claims 19 and 21 – 30, over Keana (US 5,385,946). This rejection is respectfully traversed.

It is again noted on the record that this rejection, if valid, should have been raised far earlier in the prosecution of this application. This application was filed in 2001; it is now 2008, having been through several rounds of office actions and continuations. In other words, the prosecution of this application on the part of the Patent Office has been

piecemeal in the least, and more closely resembling a bureacratic maze of hoops for Applicants to traverse.

The Examiner states that claims 19 and 21 – 30 read on the disclosure of the '946 patent, because the '946 patent teaches administration of a guanidine salt to treat hypertension. The Examiner's basis for this assumption is that the recitation of 'susceptible to' in main claim 19 is interpreted broadly to mean a person suffering from hypertension.

Applicants disagree with this interpretation of the claimed invention, and with any overlap the Examiner contrives to suit the basis for this rejection. It is simply incorrect to construe the present claims as being encompassed by a disclosure of a method to treat hypertension. Claim 19 clearly sets forth in its preamble that the method is one of "treating a prion disease in a mammal".

It was stated in the originally filed application that guanidine hydrochloride had been used in treating other conditions – there's no doubt about this. But the preamble to claim 19 carves out the 'metes and bounds' of the method to one of treating a prion disease, whereby the treatment is intended for who has the disease, or has been exposed in such a way as to put that person in the category of those who are 'susceptible' to the disease. There is no logical reason to link persons with hypertension to those persons who have, or are susceptible to, prion disease, and the rejection fails to point out such a link. The only basis for the rejection is that "...a person suffering from hypertension may be susceptible to prion disease." This is a stretch of the disclosure of the '946 patent. This patent never contemplated that a guanidine salt could be used to treat the entirely different disease and manifestations of prion diseases.

Prion diseases, while relatively rare, are devastating in how they ravage the brain and central nervous system, leading to an unimaginably cruel death. The invention in this patent application provides a way that can be used to treat animals, esp. humans, but also cattle and other animals that enter into the food chain. This method of using a guanidine salt has absolutely nothing to do with hypertension. There is absolutely no disclosure in the '946 patent to suggest that a guanidine salt could be used for such purposes. It is not inherent from the '946 disclosure (such that the present claims could possibly be interpreted to read on that disclosure), nor would one skilled in the art find it a matter of tweaking the '946 disclosure to arrive at the method of the present claims.

Moreover, the '946 patent is directed to compounds that are N,N'-disubstituted guanidines – these are not 'guanidine salts'. Applicants again request that notice be taken by the Patent Office that there is a distinct chemical difference between the compounds of the '946 patent and the salts of the present invention.

Accordingly, and particularly in consideration of the protracted prosecution of this application, Applicants implore the Examiner, on behalf of the Patent Office, to exercise his duty to withdraw this rejection and pass this application to issue. It must be remembered that the statutory law of patents puts the burden on the Patent Office to sustain reasonable grounds for refusing a patent (see 35 USC §101, "Whoever invents....may obtain a patent ..., subject to the terms and conditions of this title.", and 35 USC §102, "A person *shall be entitled* to a patent, unless..." [emphasis added]). Applicants submit that they are entitled a patent with the present claims.

Applicants gratefully acknowledge the Examiner's indication of allowability of claims 33 – 35 (if amended to include all limitations of the base claim and any intervening claims). These claims require an additional step of producing hyperthermia in the course of treatment. While Applicants agree that the methods of these claims are novel and unobvious, the rejections of the base and intervening claims are challenged on a firm basis. Therefore, Applicants are not willing to amend the claims to include the limitations of claims 33 – 35.

This response is being submitted with a Petition for two (2) months' extension of time. The Examiner is kindly invited to contact the undersigned should he believe a phone or personal interview would expedite the disposition of this application.

Respectfully submitted,

/M. Elisa Lane/
M. Elisa Lane
Attorney for Applicants
Registration No. 34,409

Panacea Pharmaceuticals, Inc.
207 Perry Parkway, Suite 2
Gaithersburg, Maryland 20877
Tel: (240) 454-8016 (direct)
elisalane@panaceapharma.com

Enclosures: Petition for Extension of Time